# IAP6 Rec'd PCT/PTO 03 MAY 2007

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John G. Babish et al.

Serial No.:

10/557.293

Filed:

November 18, 2005

Title:

Docket:

Anti-Inflammatory Pharmaceutical Compositions for Reducing inflammation and the Treatment or Prevention of Gastric Toxicity

068911-0126

Confirmation No.: :

9021

#### CERTIFICATE OF MAILING OR TRANSMISSION\

I hereby certify that this correspondence is being deposited with the U.S. Postal Service via First Class Mail in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted (571-273-3201) to the US PTO, on the date indicated below.

Date: May 1, 2007

MAIL STOP PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### TRANSMITTAL LETTER

Enclosed for filing in connection with the above-referenced patent application are the following documents:

- Information Disclosure Statement (2 pages); 1)
- 2) Information Disclosure Statement (Form PTO 1449) (5 pages);
- References cited in IDS (Form PTO 1449) B1-B17 and C1-C57; and 3)
- 4) Return Receipt Postcard.

The are no fees believed to be due with the filing of this Information Disclosure Statement. However, the commissioner is hereby authorized to charge any fees that may be required to our Deposit Account No. 50-1133.

Respectfully submitted,

Date: May 1, 2007

Atabak R. Royaee, Reg. No.: 59,037

McDermott Will & Emery LLP

28 State Street

Boston, MA 02109-1775 Telephone: (617) 535-4108 Facsimile: (617) 535-3800

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John G. Babish et al.

Serial No.:

10/557,293

Filed:

November 18, 2005

Title:

Anti-Inflammatory Pharmaceutical Compositions for Reducing inflammation and the Treatment or Prevention of Gastric Toxicity

Docket:

068911-0126

Confirmation No.:

9021

#### **CERTIFICATE OF MAILING OR TRANSMISSION**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service via First Class Mail in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted (571-273-3201) to the U.S. PTO, on the date indicated below.

Date:

May 1, 2007

MAIL STOP PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(b)

Applicants and their attorney are aware of the following publications and information, listed on the attached Form PTO-1449, and in accordance with 37 C.F.R. §§ 1.56 and 1.97(b) hereby submit these publications for the Examiner's consideration. According to the United States Patent and Trademark Office OG Notices: 05 August 2003, copies of cited U.S. patents and U.S. patent application publications are waived and not submitted with this Statement. Enclosed are copies of foreign references B1-B17, and other references cited as C1-C57. This Statement is being filed before the receipt of a first Office Action on the merits for the above-referenced application.

This Statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands that the Examiner will make an independent evaluation of the cited publications.

Application Serial No. 10/557,293

John G. Babish, et al.

Filing Date: November 18, 2005

If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited document does not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents. Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

No additional costs are believed to be due in connection with the filing of this disclosure. However, please charge any necessary fee to our Deposit Account No. 50-1133.

Respectfully submitted,

Dated: May 1, 2007

Atabak R. Royaee, Reg. No. 59,037 McDERMOTT, WILL & EMERY, LLP.

28 State Street

Boston, Massachusetts 02109-1775

Tel. (617) 535-4108 Fax: (617) 535-3800

INFORMATION DISCLOSURE CITATION IN AN APPLICATION					ATTY. DOCKET NO. 068911.0126		RIAL NO 57,293
					APPLICANT John G. Babish et al.		
		(PT	O-1449)		FILING DATE November 18, 2005	GRO To b	DUP oe assigned
				U.S. PATENT	DOCUMENTS		
EXAMINER'S INITIALS	CITE NO.		ocument Number per-Kind Code2 (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applie of Cited Document	cant	Pages, Columns, Lines, Where Relevant Passages or Relevar Figures Appear
	Al	US	3,552,975	1/5/1971	Worden,et al.		
	A7	US	3,720,517	3/13/1973	Bavisotto, et al.		
	A6	US	3,932,603	6/13/1976	Haas		
	A6	US	3,933,919	1/20/1976	Wilkinson		
	A5	US	3,965,188	6/22/1976	Westermann, et al.		
	A6	US	4,123,561	10/31/1978	Grant		
	A7	US	4,133,903	1/9/1979	Thiele, et al.		
	A6	US	4,148,873	4/10/19 <b>79</b>	Owades		
	A5	US	4,154,865	5/15/1979	Grant		
	A10	US	4,170,638	10/9/1979	Owades		
	A11	US	4,401,684	8/30/1983	Versluys		
	A12	US	4,473,551	9/25/1984	Schinitsky		
	A13	US	4,554,170	11/19/1985	Panzer, et al.		
	A13	ÜS	4,644,084	2/17/1987	Cowles, et al.		
	A15	US US	4,692,280	9/8/1987	Spinelli		,
	A16		4,767,640	8/30/1998	Goldstein, et al.		
	A17	US	4,857,554 5,006,337	8/15/1989 4/9/1991	Kallimanis Motitschke, et al.		
	A19	US	5,013,571	5/7/1991	Hay		
	A20	US	5,073,396	12/17/1991	Todd, Jr.		
	A21	US	5,082,975	1/21/1992	Todd, Jr., et al.	<del></del>	
	A22	US	5,155,276	10/13/1992	Paul	<del></del> +	
	A23	US	5,166,449	11/24/1992	Todd, Jr., et al.	$\dashv$	
	A26	US	5,286,506	2/15/1994	Millis, et al.	$\dashv$	
	A25	US	5,296,637	02/01/2000	Ting, et al.		
	A26	ÜS	5,387,425	2/7/1995	Hsu, et al.	-+	
	A27	US	5,604,263	2/18/1987	Tobe, et al.	o	
	A26	ÜS	5,624,236	11/23/1993	Ogasahara, et al.	$\neg \uparrow$	
	A29	US	5,641,517	6/24/1997	Eskeland, et al.		,
	A30	ÜS	5,827,895	10/27/1998	Nutter, et al.		gr. s <sub>emple</sub> e
	A31	US	5,968,539	10/19/1999	Beerse et al.		
	A32	ÜS	6,020,019	5/21/2002	Ting et al.		
<u> </u>	A33	US	6,129,907	2/1/2000	Sreenivasan, et al.		
·		EXA	MINER		DATE CO	ONSIDE	RED

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

INFO	CI	ГАТ	ON DISCLOS TION IN AN LICATION	SURE	ATTY. DOCKET NO. 068911.0126		RIAL NO 557,293
					APPLICANT John G. Babish et al.		
		(PT	O-1449)		FILING DATE November 18, 2005	GRC To b	0UP De assigned
				U.S. PATENT	DOCUMENTS		
EXAMINER'S INITIALS	CITE NO.		Document Number mber-Kind Code2 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Appli of Cited Document	icant	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A3 <b>2</b>	US	6,200,594	3/13/2001	Ernest et al.		
	A35	US	6,383,527	5/7/2002	Artman, et al.		
	A38	US	6,391,346	5/21/2002	Newmark, et al.		
	A37	US	6,440,465	8/27/2002	Meisner		
	A38	US	6,447,762	9/10/2002	Galcerá		
	A39	US	6,583,322	6/24/2003	Shalai, et al.		
	A40	US	6,801,860	10/5/2004	Dessen et al.		
	A41	US	20020076452	6/20/2002	Babish, et al.		
	A42	US	20020077299	6/20/2002	Babish, et al.		
	A43	US	20020086062	7/4/2002	Kuhrts		
	A44	US	20020086070	7/4/2002	Kuhrts	1	
	A45	US	20030077313	4/24/2003	Schwartz, Robert; et al.		
	A46	US	20030096027	5/22/2003	Babish, et al.		
	A47	US	20030113393	6/19/2004	Babish, et al.		
4	A48	US	20030133958	7/17/2003	Kuno, et al.		
	A49	US	20040072900	4/15/2004	Artman et al.		
	A50	US	20040086580	5/6/2004	Tripp, et al.		
	A51	US	20040137096	7/15/2004	Kuhrts		
	A52	US	20040219240	11/4/2004	Babish, et al.		
1							
					10		
EXAMINER /Michael Meller/ (11/16/2009)					DATEC	ONSIDE	RED

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

						SHEEL	3 OF 3		
INFC	CI	ATION DISC FATION IN A PPLICATION	N	ATTY. DOCKET NO. 068911.0126	1 40/557 000				
				APPLICANT John G. Babish et al.					
		(PTO-1449)		FILING DATE November 18, 2005	GROUP To be assigned				
FOREIGN PATENT DOCUMENTS									
EXAMINER'S INITIALS	CITE Document Publication Date Nan  NO. Country Codes -Number 4 - Kind Codes (if known)			Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Figures Appear	Where Figures			
						Yes	No		
	B1	DE 19841615	3/16/2000	Mueller	Abstract				
	B2	DE 2212148	9/28/1972	GEN FOODS CORP	Abstract				
	В3	DE 3931147	3/28/1991	SOLONG NATURAL LTD	Abstract				
	B4	JP 07194351	8/1/1995	Nippon Zoki Pharm Co., Ltd.	Abstract				
	B5	JP 410025247	1/27/1998	ASAHI BREWERIES LTD	Abstract				
	B6	JP 10152428	6/9/1998	Kanebo Ltd	Abstract				
	B7	JP 9067245	3/11/1997	Ashai Breweries, Ltd.	Abstract				
	B6	JP 04202138	7/22/1992	Asahi Breweries Ltd	Abstract				
	B4	JP 6312924	11/8/1994	Asahi Breweries Ltd	Abstract				
	B10	JP 363211219	9/2/1988	TAIYO KORYO KK	Abstract				
	B11	JP 8073369	3/19/1996	Kubo M	Abstract				
	B12	RU 2045955	10/20/1995	Nikitina	Abstract				
	B13	SU 1247011	7/30/1986	SP K B KHIM N PROIZV OBEDINENI					
	B14	WO 00/68356	11/16/2000	Yakima Chief, Inc.					
	B15	WO00/74696	12/14/2000	OXFORD NATURAL PRODUCTS PLC					
	B16	WO02/02582	1/10/2002	Deutsches					
	B17	WO99/44623	9/10/1999	NPS PHARMA INC					
							_		
				ithor, Title, Date, Pertinent Pages, Etc	•				
EXAMINER'S INITIALS	CITE NO.		nal, serial, symposiu	ETTERS), title of the article (when ap um, catalog, etc.), date, page(s), volur	propriate), title of t ne-issue number(s	the item s), publisher	·,		
		See sheet Nos. 4-5							
					•				
	<u> </u>	EXAMINER			0010105555				
/Michael M	Michael Meller/ (11/16/2009)								

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION			ATTY. DOCKET NO. 068911.0126	SERIAL NO 10/557,293				
			APPLICANT John G. Babish et al.					
		(PTO-1449)	FILING DATE November 18, 2005	GROUP To be assigned				
		OTHER ART (Including Autho	r, Title, Date, Pertinent Page	s, Etc.)				
EXAMINER'S INITIALS								
	CI	"Information on ArthroTrim™ product", do	ownloaded from Internet 8/30/02.					
	C2	"Information on Zyflamend and Zyflamend	PM", downloaded from Internet 8/	30/02.				
<del></del>	C3	"Information on Hops and Beer Flavours",						
	C4	Anto, et al. Pharm. Pharmacol. Comm. 4:10						
<del></del>	C5	Bermejo, et al. Rev. Esp. Enferm. Dig. 95(9	2): 625-628 (2003)					
•	C6	Brown, et al. J. Chem. Soc. 545 (1959)						
	C7	Byrne, et al. J. Chem. Soc. (c):2810-2813 (	1971)					
	C8	Carroccio, et al. Clin. Chem. 49(6):861-867	7 (2003)					
	C9	Carson, J., Am. Chem. Soc. 73:1850-1851 (						
	C10	Chandra, et al. Indian J. Medical Research 60(1):138-142 (1972)						
	Cll		Charlier, et al. Eur. J. Med. Chem. 38:645-659 (2003)					
	C12	CHOU et al. Eur. J. Biochem. <u>115</u> :207-216 (1981)						
	C13	Chou, et al. Adv enzyme regul 22:27-55 (19	983)					
	C14	Chou, et al. J. Biol. Chem. <u>252(18)</u> :6438-6442 (1977)						
	C15	Chou, et al. J. Theor. Biol. <u>35</u> :285-297 (1972)						
	C16	Chou, et al. Trends Pharm. Sci. 4:450-454 (	33)					
	C17	Chou, J. Theor. Biol. <u>59</u> :253-276 (1976)						
	C1 <del>0</del>	Costa, et al. Digest. Liver Dis. 35:642-647	(2003)					
	C19	Davies, WL. Abstract - Fertiliser, Feeding S		(1926)				
	C20	Ding, et al. Biochem. Biophy. Res. Comm.						
	C21	Friedman, et al. J Cutan Med. Surg. 6(5):44						
	C22 Germany, "The Absolutely German Drink," contents of beer, 2004, 5 pages.							
	C23	Goldstein, et al. Am. J. Gastroenterol. 96(4)	):1019-1027 (2001)					
	C24	Halter, et al. Gut 49:443-453 (2001)						
	C25	Hamberg, et al. J. Bio. Chem. 246(22):6713						
	C26	Huang, et al. Cancer Res. 51:813-819 (1991						
**************************************	C27	International Search Report for PCT/US02/19617						
	C28	International Search Report for PCT/US04/						
	C29		Jach, Przegl Dermatol. 65(4):379-381 (1978)					
	C30	· · · · · · · · · · · · · · · · · · ·						
	C31	Lopes, Curr. Med Res Opin. 8(3):145-149 (Meling, et al. Scand. J. Gastroenterol. 31:33						
	1032	memig, et al. bealla. J. Gastroenterol. 31.55	77 377 (1770)					
	1							
<del></del>	1							
		EXAMINER	DATE	CONSIDERED				
/Michael Me	eller/ (11.		DATE	CONSIDENCE				

SHEET <u>5</u> OF <u>5</u>

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

INIEC	DAG	ATION DIGGLOSURE	Time population	SERIAL NO				
INFC		ATION DISCLOSURE	ATTY. DOCKET NO. 068911.0126	10/557,293				
	CI'	TATION IN AN	088911.0126					
	A	APPLICATION						
			APPLICANT					
			John G. Babish et al.					
		(PTO-1449)	FILING DATE	GROUP				
			November 18, 2005	To be assigned				
		OTHER ART (Including Autho	r, Title, Date, Pertinent Page	es, Etc.)				
EXAMINER'S	l	Include name of the author (in CAPITAL LET	TERS), title of the article (when ap	propriate), title of the item				
INITIALS	CITE NO.							
	C33	Noreen, et al. J. Nat. Prod 61:2-7 (1998)						
	C34	Pairet, et al. Inflamm. Res 47(2), s93-s101 (1998)						
	C35	Panglisch, monafsschrift fuer brauwissen schaft, 1990, 43(1), 4-16						
	C36	Pippa, et al. Scand. J. Gastroenterol. 32-35 (1989)						
	C37	Plewig, et al. J Invest. Dermatol. 65(6):532-536 (1975)						
	C38							
	C39							
	C40 C41	Røseth, Digest. Liver Dis. <u>35</u> :607-609 (2003)  Schjerven, <i>et al.</i> Br. J. Dermatol. 149:484-491 (2003)						
	C42	Shah, et al. Gut <u>48</u> :339-346 (2001)						
	C43	Shimamura, et al. Biochem. Biophys. Res. Comm. 289:220-224 (2001)						
	C44	Shureiqi, et al. Cancer Res. 61:6307-6312 (						
	C43							
	C47	Subbaramaiah, et al. Cancer Res. <u>60</u> :2399-2404 (2000)  Suh, et al. Cancer Res. <u>58</u> :717-723 (1988)						
	C48							
	C49	Thomas m. Newmark and paul schulick, 'Beyond Aspirin nature's answer to arthritis, cancer & alzheimer's						
		disease," hohm press (2000) release 7; pp. 147-151.						
	C50	Tibble, et al. Drugs Today 37(2):85-96 (2001)						
	C51	Tibble, et al. Gut 45:362-366 (1999)						
	C52	Tobe, et al. Biosci. Biotech. Biochem <u>61(1):158-159 (1997)</u>						
	C53	Wang, et al. Free Radical Biology & Medicine <u>27(5/6)</u> :612-616 (1999)						
	C54							
	C55	Yamamoto, et al. Abstract - Prostaglandins & Other Lipid Mediators 59:1-235 (1999)  Yamamoto, FEBS Letters 465:103-106 (2000)						
	C57	Yui, et al. Biol. Pharm. Bull. 26(6):753-760	(2003)					
<del></del>	-							
	<del>                                     </del>							
	<del> </del>							
		EXAMINER	DATE	CONSIDERED				
/Michael	Meller/ (	11/16/2009)	DATE					

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.